



Docket No.: NY-HUBR 1230-US  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Chris Rundfeldt et al.

Application No.: 10/680,459

Confirmation No.: 4494

Filed: October 6, 2003

Art Unit: 1617

For: USE OF DIHYDROIMIDAZOLONES FOR  
THE TREATMENT OF DOGS

Examiner: D. R. Claytor

**COMMUNICATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In connection with this RCE application, applicants comment as follows:

In the final rejection of December 9, 2008:

“(T)he Examiner takes the stand that both dogs and humans have idiopathic epilepsy and treatment regimes for both may possibly be similar.”

The attached Declaration of Dr. med. Vet. Holger Volk (“Volk” hereafter) and Univ.- Prof. Dr. med. Vet. Marc Vandevelde (“Vandevelde” hereafter) refute this.

The credentials of Volk and Vandevelde, as reflected in their curricula vitae, speak for themselves.

The Volk Declaration, at paragraph 5, for example, discusses how medications, suitable for use in humans, are not suitable for canines with idiopathic epilepsy. As Volk explains, there was a lack of efficacy and the existence of toxicity, in some cases.

Vandevelde confirms this, in his Declaration at paragraph 10, for example. Indeed, Vandevelde points to published studies where a failed attempt was made to validate the epileptic dog as a model for human epilepsy. The study is attached to the Vandevelde Declaration.

The Vandevelde Declaration goes on to explain, at paragraphs 11 and 12, for example, that even compounds that were validated in the models used in the reference of record, did not actually work in dogs. See paragraph 11, and the studies cited therein, and then paragraph 12, for an explanation extrapolating the models in the literature to canines.

Regarding the particulars of the rejection, Volk and Vandevelde have considered the references, as is seen, e.g., in paragraphs 5-7 of the Vandevelde Declaration, and then paragraphs 8 and 9, discussing the lack of applicability in other models. Please also note the Volk Declaration, paragraphs 2 and 9, for example, discussing Bialer.

Both Volk and Vandevelde provide detailed reasons for their conclusions, especially the fact that the canine gastrointestinal system is rather unique. Please note the Vandevelde Declaration, paragraph 13; generally, and paragraphs 14 and 15 for the compound claimed, and the Volk Declaration, paragraphs 8 and 9, dealing with canine treatment generally (paragraph 8), and the compound set forth in the claims, at paragraph 9.

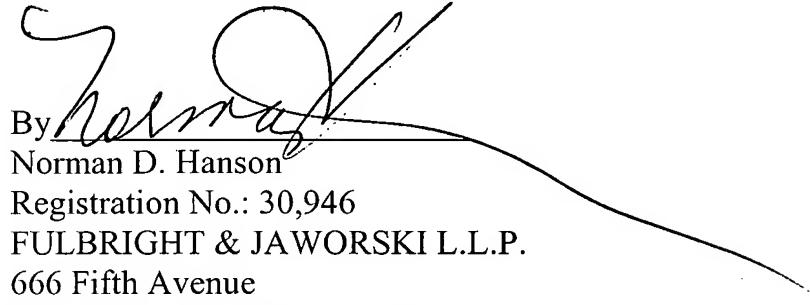
In view of the accompanying materials, it is believed that the Examiner should reconsider and withdraw the rejections, and pass this case to issue.

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The Commissioner is hereby authorized to deduct any fees associated with this filing from our Deposit Account No. 50-0624, under Order No. NY-HUBR 1230-US (10312533) from which the undersigned is authorized to draw.

Dated: 6/31/03

Respectfully submitted,

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